

REMARKS

Claims 1-3, 5-10, 12, and 14-19 are pending. The Office Action is discussed below:

Claim Rejection under USC § 103

On pages 2-3 of the office action, the examiner rejected claims 1-3, 5-10, 12, and 14-19 allegedly as being unpatentable over Ohtsuka et al. (US 6,372,735). The examiner refers to the compound of Example 20 of Ohtsuka et al. (see Ohtsuka et al., col. 42, line 15 to col. 43 line 34) and alleges that Ohtsuka et al. discloses the crystalline form of the claimed compound. The examiner believes in view of Hancock et al. (Pharma Res, Vol. 17, No. 4, 2000) that amorphous compounds are more soluble than their crystalline counterparts, one skilled in the art would be motivated to convert crystalline pharmaceuticals into their amorphous counterparts and arrive at the claimed invention.

Applicants respectfully disagree because the examiner has failed to establish a *prima facie* case of obviousness and submit that:

To establish a *prima facie* case of obviousness, at least two criteria must be met. First, there must be some motivation or suggestion to make the proposed combination or modification of the references. Further, "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." MPEP 2142 (Rev. 3, August 2005), discussing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In addition, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." Also see MPEP 2143-2143.03 (Rev. 3, August 2005). (emphasis added).

The question of patentability, however, does not revolve upon whether the prior art instills the skilled person with some type of desire to undertake inventive efforts, but rather whether the prior art suggests the claimed subject matter itself to the person of ordinary skill in the art. See *Gillette Co. v. S.C. Johnson & Son*, 10 USPQ2d 1923,

1928 (Fed. Cir. 1990); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988) (holding that a reference that invites experimentation or renders something 'obvious to try' cannot satisfy the strictures of 35 USC § 103).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). See *U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). (emphasis added). Applicants submit that the rejections do not meet this test.

Applicants also submit following arguments to overcome the 35 USC § 103 rejection:

The teaching or suggestion to make the claimed amorphous compound and the reasonable expectation of success are not present in Ohtsuka et al. and Hancock et al. According to the examiner, Hancock et al. discloses that "amorphous compounds are more soluble than their crystalline counterparts", however, Hancock et al. or Ohtsuka et al. does not teach any method to arrive at the claimed invention.

On page 3 of the office action, the examiner asserts that the "process of spray-drying to yield amorphous compounds is known", which is also discussed in instant specification (See page 2, line 24). However, Hancock et al. and Ohtsuka et al. do not teach or suggest all the claim limitations (for example, the method steps according to claims 6-9) to arrive at the claimed amorphous compounds.

Applicants also submit that with respect to the crystalline form of the Compound A, it was difficult to convert the crystal form of the Compound A to its amorphous form. The difficulties of obtaining an amorphous form using the methods known in the art are discussed in instant application (see specification, for example, page 2, line 19 to page 3, line 3). Besides, applicants had to carry out many experiments to arrive at the

claimed amorphous form of the Compound A. Although applicants failed to obtain the amorphous Compound A using several methods known in the art, as discussed in the specification (see specification, for example, page 2, line 19 to page 3, line 3), finally arrived at the claimed amorphous Compound A using the recited methods, as disclosed in the specification. Therefore, it would not be obvious to an skilled artisan to arrive at the claimed amorphous Compound A and the methods to arrive at the claimed inventions by combining the Crystalline compound of Ohtsuka et al. and the statement of Hancock et al. that "amorphous pharmaceuticals are more soluble than their crystalline counterparts", unless there is a suggestion to make the claimed combination and the reasonable expectation of success are present in the cited arts.

Withdrawal of the obviousness rejection is therefore solicited.

REQUEST

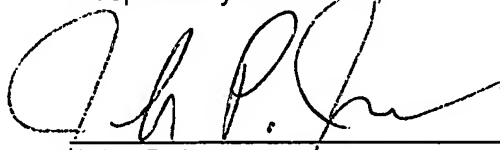
In view of above remarks, applicants respectfully submit that claims 1-3, 5-10, 12, and 14-19 are allowable, and respectfully request favorable consideration to that effect. The Examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

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Date

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Respectfully submitted,



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